

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of LI *et al.*

Group Art Unit: 1616

Application Serial No.: TBD

Examiner: Hartley, M.

Filed: July 14, 2003

Docket No.: 1401S

For: WATER SOLUBLE PACLITAXEL DERIVATIVES

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

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The attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached Form SB-08. The references have been submitted to the Examiner in the parent application and are not attached herewith. Additional copies of references are available on request. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 CFR 1.97(b)(1)(2)(3).
2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance. 37 CFR 1.97(c)(1)(2).
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- c. Please debit or credit the \$240.00 fee to Account No. 03-1182 under 37 C.F.R. 1.17(p), or as needed to ensure consideration of the disclosed information. A duplicate copy of this paper is attached.
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Applicants respectfully request that the listed documents be considered by the Examiner and formally be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609. The references listed in the attached SB-08 have been submitted in the parent application. Additional copies are available on request.

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Respectfully submitted,

By: 
Donald W. Wyatt, Reg. No. 40,879
Attorney for Applicants

Date: July 14, 2003

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 STATEMENT BY APPLICANT**
 Date Submitted: March 22, 2002
 (use as many sheets as necessary)

Sheet 1 of 11

Complete if Known

Application Number	
Filing Date	July 14, 2003
First Named Inventor	LI
Group Art Unit	1616
Examiner Name	Hartley
Attorney Docket Number	1401S

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document Number	Kind Code ² (# known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
A1	2001/0034363	A1		Li et al.	10/25/2001	
A2	2002/0016285	A1		Bhatt et al.	02/07/2001	
A3	4,356,166			Peterson et al.	10/26/1982	
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Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: March 22, 2002 <i>(use as many sheets as necessary)</i>				Complete If Known	
Sheet	2	of	11	Application Number	
				Filing Date	July 14, 2003
				First Named Inventor	LI
				Group Art Unit	1616
				Examiner Name	Hartley
				Attorney Docket Number	1401S

U.S. PATENT DOCUMENTS

		U.S. Patent Document			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
A54	WO	93/10121	A1	Hans (w/Abstract)	05/27/1993			
A55	JP	5286868	A	Kiyoshi et al. (w/Abstract)	11/02/1993			
A56	WO	95/03036	A1	Hunter et al.	02/02/1995			
A57	WO	95/13053	A1	Straubinger et al.	05/18/1995			
A58	EP	0589281	B1	Gasteler (w/Abstract) **	03/13/1996			
A59	WO	96/25176	A1	Kunz et al.	08/22/1996			
A60	EP	0558959	B1	Uedal et al.	04/16/1997			
A61	WO	97/33552	A1	Li et al.	09/18/1997			
A62	WO	99/17804	A1	Angelucci et al.	04/15/1999			
A63	WO	99/49901	A1	Li et al.	10/07/1999			
A64	EP	0604910	B1	Golik et al.	06/14/2000			
A65	WO	01/70275	A2	Bhatt et al.	09/27/2001			

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
A66		BALOG ET AL., "Total Synthesis of (-) Epothilone A," <i>Angew. Chem. Int. Ed. Engl.</i> , Vol. 35, 1996, pp. 2801-2803 © VCH Verlagsgesellschaft mbH, Weinheim	
A67		BARTOLI ET AL., "In Vitro and In Vivo Antitumoral Activity of Free, and Encapsulated Taxol," <i>J. Microencapsulation</i> , Vol. 7, 1990, pp. 191-197 © Taylor & Francis Ltd.	
A68		BOM ET AL., "The Novel Siliatecan 7-tert-Butyldimethylsilyl-10-hydroxycamptothecin Displays High Lipophilicity, Improved Human Blood Stability, and Potent Anticancer Activity," <i>Journal of Medicinal Chemistry</i> , Vol. 43, No. 21, 2000, pp. 3970-3980, © American Chemical Society	
A69		BORMAN, S., "Epothilone Epiphany: Total Syntheses," <i>C&EN</i> , Vol. 74, 1996, pp. 24-26 © American Chemical Society	

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Sheet	3	of	11	Application Number	
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				Group Art Unit	1616
				Examiner Name	Hartley
				Attorney Docket Number	1401S

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
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	A70	CAIOLFA ET AL., "Polymer-bound camptothecin: initial biodistribution and antitumor activity studies," <i>Journal of Controlled Release</i> , Vol. 65, 2000, pp. 105-119, © Elsevier Science B.V.			T ⁶
	A71	CONOVER ET AL., "Camptothecin delivery systems: enhanced efficacy and tumor accumulation of camptothecin following its conjugation to polyethylene glycol via a glycine linker," <i>Cancer Chemother Pharmacol</i> , Vol. 42, 1998, pp. 407-414, © Springer-Verlag			
	A72	CONOVER ET AL., "Camptothecin Delivery Systems: The Utility of Amino Acid Spacers for the Conjugation of Camptothecin with Polyethylene Glycol to Create Prodrugs," <i>Anti-Cancer Drug Design</i> , Vol. 14, 1999, pp. 499-506, © Oxford University Press			
	A73	CONOVER ET AL., "Camptothecin Delivery Systems: The Antitumor Activity of a Camptothecin-20-O-Polyethylene Glycol Ester Transport Form," <i>Anticancer Research</i> , Vol. 17, 1997, pp. 3361-3368			
	A74	CORTES ET AL., "Docetaxel," <i>J. of Clinical Oncology</i> , Vol. 13, 1995, pp. 2643-2655 © American Society of Clinical Oncology			
	A75	DE BONO ET AL., "Phase I Pharmacokinetic (PK) Study of Mag-CPT-(PNO 166148) A Polymer Derivative of Camptothecin (CPT)," <i>Pharmacia</i>			
	A76	DE VRIES ET AL., "Conjugation of Docetaxel (DTXL) to Poly L-Glutamic Acid (PG) Increases Anti-Tumor Efficacy," <i>Proceedings of the American Association for Cancer Research</i> , Vol. 41, 2000, pg. 323, Abstract No. 2051			
	A77	DE VRIES ET AL., "CT-2103: A water soluble poly-L-glutamic acid (PG)-Paclitaxel (TXL) conjugate has enhanced efficacy on MDR-1+human colon carcinoma cell line xenografts compared to free TXL," <i>AACR</i> , 2001, Abstract No. 462			
	A78	DE VRIES ET AL., "Optimization of the anti-tumor activity of water-soluble poly L-glutamic acid (PG)-paclitaxel (TXL) conjugates," <i>AACR-NCI-EORTC</i> 92, 1999, p. 22, Abstract No. 451, Washington, DC			
	A79	DE VRIES ET AL., "Pharmacokinetics (PK) and biodistribution of poly-(L)-glutamic acid (PG) paclitaxel (TXL) (CT-2103) in mice with subcutaneous B-16 melanomas," <i>Proceedings of the 11th AACR-NCI-EORTC Symposium</i> , 2000 Amsterdam, Netherlands			
	A80	DEUTSCH ET AL., "Synthesis of Congeners of Prodrugs. 3. Water-Soluble Prodrugs of Taxol with Potent Antitumor Activity," <i>J. Med. Chem.</i> , Vol. 32, 1989, pp. 788-792 © American Chemical Society			
	A81	DUNCAN ET AL., "Polymer-drug conjugates, PDEPT and PELT: basic principles for design and transfer from the Laboratory to Clinic," <i>Journal of Controlled Release</i> , Vol. 74, 2001, pp. 135-146, © Elsevier Science B.V.			
	A82	EISEMAN ET AL., "Plasma pharmacokinetics and tissue distribution of paclitaxel in CD2F1 mice," <i>Cancer Chemother. Pharmacol.</i> , Vol. 34, 1994, pp. 465-471 © Springer-Verlag			

Examiner Signature		Date Considered	
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	A83	FIDLER ET AL., "The Biology of Cancer Invasion and Metastasis," <i>Adv. Cancer Res.</i> , Vol. 28, 1978, pp. 149-250 © Academic Press, Inc.	
	A84	GILBERT ET AL., "Novel water soluble paclitaxel derivatives: Evaluation of PEG-paclitaxel's <i>in vitro</i> and <i>in vivo</i> effects," <i>Proc. Amer. Assoc. Cancer Res.</i> , Vol. 38, 1997, pg. 225, Abstract #1512	
	A85	GOLDSPIEL, "Pharmaceutical Issues: Preparation, Administration, Stability, and Compatibility with Other Medications," <i>Ann. Pharmacotherapy</i> , Vol. 28, 1994, pp. S23-26, © Harvey Whitney Books Company	
	A86	GREENWALD ET AL., "Camptothecin-20-PEG Ester Transport Forms: the Effect of Spacer Groups on Antitumor Activity," <i>Bioorganic & Medicinal Chemistry</i> , Vol. 6, 1998, pp. 551-562, © Elsevier Science Ltd.	
	A87	GREENWALD ET AL., "Drug Delivery Systems. 2. Camptothecin 20-O-Poly(ethylene glycol) Ester Transport Forms," <i>J. Med. Chem.</i> , Vol. 39, 1996, pp. 1938-1940, © American Chemical Society	
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	A89	GREENWALD ET AL., "Highly Water Soluble Taxol Derivatives: 2'-Polyethylene Glycol Esters as Potential Products," <i>J. Org. Chem.</i> , Vol. 60, 1995, pp. 331-336 © American Chemical Society	
	A90	GREENWALD ET AL., "Highly Water Soluble Taxol Derivatives: 2'-polyethyleneglycol esters as potential prodrugs," <i>Bioorganic & Medicinal Chemistry Letters</i> , Vol. 4, 1994, pp. 2465-2470 © Elsevier Science Ltd.	
	A91	GREENWALD ET AL., "Stereoselective acylation of 20-(S)-camptothecin with amino acid derivatives using scandium triflate/DMAP," <i>Tetrahedron: Asymmetry</i> , Vol. 9, 1998, pp. 915-918, © Elsevier Science Ltd.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
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Sheet	5	of	11	Group Art Unit	1616
				Examiner Name	Hartley
				Attorney Docket Number	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	A92	GREENWALD, "Camptothecin-20-PEG Ester Transport Forms: the Effect of Spacer Groups on Antitumor Activity", <i>Bioorganic & Medicinal Chemistry</i> , Vol. 6, 1998, pp. 551-562 © Elsevier Science Ltd.			
	A93	HIRANO ET AL., "Polymeric derivatives of activated cyclophosphamide as drug delivery systems in antitumor therapy pharmacologically active polymers, 20," <i>Makromol. Chem.</i> , Vol. 180, 1979, pp. 1125-1130 © Hüthig & Wepf Verlag, Basel, Heidelberg			
	A94	HOES ET AL., "Optimization of macromolecular prodrugs of the antitumor antibiotic adriamycin," <i>J. Controlled Release</i> , Vol. 2, 1985, pp. 205-213 © Elsevier Science Publishers B.V.			
	A95	HÖFLE ET AL., "Epothilone A and B – novel 16-membered macrocycles with cytotoxic activity: isolation, crystal structure, and conformation in solution," <i>Angew. Chem. Int. Ed. Engl.</i> , Vol. 35, 1996, pp. 1567-1569 © VCH Verlagsgesellschaft mbH			
	A96	HORWITZ ET AL., "Taxol, mechanisms of action and resistance," <i>J. Natl. Cancer Inst. Monographs</i> , Vol. 15, 1993, pp. 55-61			
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Examiner Signature	Date Considered
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Sheet	6	of	11	Attorney Docket Number
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		
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	A102	KOUSKOFF ET AL., "Organ-specific disease provoked by systemic autoimmunity," <i>Cell</i> , Vol. 87, 1996, pp. 811-822 © Cell Press		
	A103	KUANG ET AL., "Poly(benzyl-L-glutamate) microcapsules: Their diagnostic and therapeutic potential," <i>Pharm. Res.</i> , Vol. 10, 1993, pg. S-191, Abstract PDD 7066 © Plenum Press		
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				Group Art Unit	1616
				Examiner Name	Hartley
				Attorney Docket Number	1401S

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	A110	LI ET AL., "Synthesis and evaluation of water-soluble polyethylene glycol-paclitaxel conjugate as a paclitaxel prodrug," <i>Anticancer Drugs</i> , Vol. 7, 1996, pp. 642-618			
	A111	LI ET AL., "Complete regression of well-established tumors using a novel water-soluble poly(L-glutamic acid)-paclitaxel conjugate," <i>Cancer Res</i> , Vol. 58, 1998, pp. 2404-2409			
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	A113	LI ET AL., "Enhancement of tumor radioresponse of a murine ovarian carcinoma by poly(L-glutamic acid)-paclitaxel conjugate," <i>Ninth International Symposium on Recent Advances in Drug Delivery Systems</i> , 1999, Salt Lake City, UT			
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	A117	LI ET AL., "Potentiation of ovarian OCa-1 tumor radioresponse by poly (L-glutamic acid)-paclitaxel conjugate," <i>Int J Radiat Oncol Biol Phys</i> , Vol. 48, 2000, pp. 1119-1126 © Elsevier Science Inc.			
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	A119	MAGRI ET AL., "Modified Taxols. 2. Oxidation Products of Taxol," <i>J. Org. Chem.</i> , Vol. 51, 1986, pp. 797-802 © American Chemical Society	
	A120	MATHEW ET AL., "Synthesis and evaluation of some water-soluble prodrugs and derivatives of taxol with antitumor activity," <i>J. Med. Chem.</i> , Vol. 35, 1992, pp. 145-151 © American Chemical Society	
	A121	MASON ET AL., "Poly (L-glutamic Acid)-paclitaxel dramatically enhances the anti-tumor efficacy of radiotherapy," AACR - NCI - EORTC, Vol. 397, 2001, Miami Beach, Florida	
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	A124	MOSMANN, "Rapid colorimetric assay for cellular growth and survival: application to proliferation and cytotoxic assay," <i>J. Immunol. Methods</i> , Vol. 65, 1983, pp. 55-63 © Elsevier Science Publishers B.V.	
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	A126	PESENTI ET AL., "Synthesis and biological activity of water soluble polymer-bound taxol derivatives," <i>Proc. Amer. Assoc. Cancer Res.</i> , Vol. 36, 1995, p. 307, Abstract No. 1824.	
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	A129	REYNOLDS ET AL., "Polymers help guide cancer drugs to tumor targets- and keep them there," <i>J. Natl. Cancer Institute</i> , Vol. 87, 1995, pp. 1582-1584			
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	A137	SINGER ET AL., "Conjugation of Camptothecins to Poly-(L-Glutamic Acid)," <i>Annals of the New York Academy of Sciences</i> , Vol. 922, 2000, pp. 135-150, © The New York Academy of Sciences	
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	A148	YU, "Effect of polymer structure on antitumor activity of polyaminio acid-paclitaxel conjugates," <i>Proc. Amer. Assoc. Cancer Research</i> , Vol. 39, 1998, p. 167, Abstract No. 1144		
	A149	ZHANG ET AL., "An investigation of the antitumor activity and biodistribution of polymeric micellar paclitaxel," <i>Cancer Chemother. Pharmacol.</i> , Vol. 40, 1997, pp. 80-86 © Springer-Verlag		
	A150	ZHAO ET AL., "Modified taxols. 6. preparation of water-soluble taxol phosphates," <i>J. Nat. Prod.</i> , Vol. 54, 1991, pp. 1607-1611		
	A151	ZHENG ET AL., "Deacetylation of Paclitaxel and Other Taxanes," <i>Tetrahedron Letters</i> , Vol. 36, 1995, pp. 2001-2004, © Elsevier Science Ltd.		
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